Important FDA Regulatory Information

MicroGEM Sal6830 Point of Care PCR System
MicroGEM Sal6830 SARS-CoV-2 Saliva Test

The MicroGEM Sal6830 SARS-CoV-2 Saliva Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. The MicroGEM Sal6830 SARS-CoV-2 Saliva Test is also authorized for laboratories certified under the clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform, high, moderate or waived complexity tests.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

For more information: https://microgembiocovid19.com/contact/